Reflections on regulatory oversight of nuclear power plants

Björn Wahlström

Technical Research Centre of Finland,
VTT Organizations, networks and innovation systems, POB 1000
Visiting address: Vuorimiehentie 5, FIN-02044 VTT (Espoo), Finland
E-mail: Bjorn.Wahlstrom@vtt.fi

Abstract: A regulatory body acts as a representative for society to ensure that the operation of nuclear facilities do not introduce any undue threats. Typical regulatory tasks include the definition of safety requirements, the inspections needed to ensure that they are adhered to and the imposing of sanctions if violations are detected. Regulatory oversight is anchored in national legislation, which is defining objectives and procedures. Regulatory oversight has, in the nuclear power field an important role in ensuring the continued safety of the facilities. It is, therefore, prudent to ask the question, what requirements should be placed on regulatory oversight to make them effective? The main conclusion of the paper is that a successful regulatory oversight relies on a thorough understanding of the role of being a regulator in relation to the regulated industry.

Keywords: nuclear power plants; nuclear safety; regulatory oversight.

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Biographical notes: Björn Wahlström was educated at the Helsinki University of Technology (MSc 1967, PhD 1971). He has been employed at the Technical Research Centre of Finland (VTT) since 1971, where he was appointed Laboratory Director and Professor in 1985. During 1989–1991 he was on a leave of absence working at the International Institute for Applied Systems Analysis in Laxenburg, Austria. Since 1994, he has been working as Research Professor in systems engineering at VTT. He is a past or present member of several working groups of IAEA and OECD/NEA. He was the Co-ordinator of the EU-funded project LearnSafe. He has written more than 250 papers in the fields of systems engineering, simulation, control and instrumentation, nuclear power, control room design, human factors, organisation and management, risk analysis and technology management.

1 Introduction

This paper was originally written as a part of the LearnSafe project,[1] which studied the *management of change* and *organisational learning*. The LearnSafe project was only indirectly connected to regulatory oversight through the participating nuclear power plants. However, a considerable amount of the data collected in the project made reference to regulation and regulatory actions and it was, therefore, justified to assemble a specific paper on regulatory oversight. The paper is targeted at nuclear safety but other regulatory regimes also may find the paper interesting.

A regulatory body acts as a representative for the society to ensure that the operation of nuclear facilities do not introduce any undue threats. Typical regulatory tasks include the definition of safety requirements, the inspections needed to ensure that they are adhered to and the imposing of sanctions if violations are detected. Regulatory oversight is anchored in national legislation, which is defining regulatory ends and means in more detail. National regulatory practices differ, partly due to historical reasons and partly due to selected regulatory strategies.

In the nuclear field it is usual to restrict the scope of regulatory oversight to nuclear safety and radiation protection. This implies that certain functions, systems and practises at the nuclear facilities are considered more important than others as targets for the regulatory attention. A common approach has been to use some classification such as, for example, to separate between safety, safety related and non-safety issues. Such a classification has the benefit of making it easier to target regulatory oversight to important issues but it has the difficulty of being somewhat arbitrary, especially in the borderlines between the classes.

Regulatory oversight has an important role in ensuring the continued safety of nuclear power. It is, therefore, prudent to ask the question, what requirements should be placed on regulatory oversight? It is well known that regulatory views and actions sometimes cause controversies between the regulator and licensees and a follow up question is, therefore, how such controversies can be minimised to maintain a constructive dialogue between the parties. In addressing the impact and efficiency of regulatory oversight, it is necessary to assess its legitimacy, mission and practices in a broad sense. From this standpoint the paper makes an attempt to identify good regulatory practices with the assumption that they could improve the safety of the nuclear facilities. The position of the paper is that an early identification and resolution of possible problems in the interface between the regulator and the licensees can make the regulatory oversight more effective and, therefore, contribute to an increased safety of the nuclear facilities.

The paper is divided into five further sections, the first of which lays out the main principles in the construction and verification of safety. These principles form the basis for regulatory oversight and they are interpreted both in safety requirements and used practices for regulatory oversight. Section three gives an overview of typical regulatory practices, which are used in the nuclear field. Section four considers various challenges that can be identified from present regulatory practices. Section five gives an account of typical complaints on regulatory oversight that can be heard at the nuclear facilities. Section six discusses a few issues that seem to be crucial in a further development of regulatory oversight in the nuclear field. The main conclusion of the paper is that a successful regulatory oversight relies on a thorough understanding of two roles, i.e. on one hand the role of being a regulator and, on the other hand, the role of being a part of a regulated industry.

2 Construction and verification of safety

Nuclear safety builds on a set of general safety principles that are applied in the design and operation of the facilities. These principles have been developed over time by analysing failure mechanisms and failure propagation and by applying methods of safety engineering to the technical, human and organisational systems at the nuclear facilities. The principles lay the basis for the design and operation of the facilities, as well as for regulatory oversight. An understanding of regulatory practices builds on an understanding of how these general safety principles are interpreted and converted into tangible evidence that design and operation of the facilities fulfils applicable requirements on safety. This chapter aims to paint a broad picture of how these principles are applied in both the construction and the verification of nuclear safety.

2.1 Defence in depth

The most important of the safety principles is the defence in depth principle (IAEA, 1996). According to this principle, multiple independent barriers are erected against unwanted courses of events. The principle implies that protection at one level always is supported by protection at the next level to ensure safety, even if the primary protection would fail. Another way to view this safety principle is to see it in a set of consecutive barriers or actions, where the task of the first protective barrier is to prevent possible safety threats by eliminating initiating events. The second barrier of defence is to control sequences of events by confining harmful consequences in various steps of the chain. The final barrier is erected through mitigation activities in case a sequence of events bypasses the first two barriers.

The defence in depth principle can be used to suggest other derived safety principles. One of these principles is the single failure principle, which implies that no single failure should be allowed to pose a threat to the safety of the facility. This principle leads to the introduction of requirements on redundancy, diversity and separation. It also is connected to the grace requirement, where control room operators, for example, should have at least 30 min after a major plant incident to select their course of action to bring the facility into a safe state.

The defence in depth principle and its derivatives has been applied with large success to the technical systems. Unfortunately, it has proved to be more difficult to apply in a consistent way to the human and organisational systems.

2.2 Deterministic and probabilistic safety principles

The second level in the design for safety is to apply certain deterministic and probabilistic principles by which candidate designs can be analysed regarding their acceptability. The deterministic design principles are expressed in terms of certain design basis accidents (DBA), which act as probing stones for safety provisions within the design. The DBAs are anticipated events within which the plant responses to certain initiating events are analytically verified. They provide a set of envelopes within which certain coverage in the safety precautions is demonstrated. However, it is understood that less frequent events of greater complexity will occur and that more severe accidents, though unlikely, remain possible. The analysis of the design can, thus, be carried out by analysing plant responses to certain initiating events to ensure that all threats are properly responded to.

The probabilistic safety principles use a different approach. In the recognition that there always is a non-zero probability that a certain system and its backup will fail, the probabilistic design principles make an attempt to define reliability targets for important safety functions and systems to ensure that the expected frequency for large accidents can be kept small enough. A typical design target is, for example, that the frequency of core melt should be lower than once in 100,000 years and that a release of large amounts of radioactivity should be at least one order of magnitude less frequent.

The deterministic and probabilistic safety principles complement each other. If, for example, a deterministic requirement on redundancy can be shown to be very unlikely to be required using probabilistic arguments, an exemption from the deterministic principles may be granted. Similarly, if a certain sequence of events can be argued to have been made practically impossible by deterministic means, it may be excluded from the probabilistic models of failure causation and propagation.

2.3 Systems of requirements

The application of the safety principles is typically supported through the development of more detailed requirements on design and operation. This development can be seen as progressing through a kind of means-ends hierarchy, where ends on a higher level are taken care of by certain means on a lower level. One may, therefore, speak about a system of requirements in which there is a certain hierarchical relationship between single requirements.

In the definition of systems of requirements one aim has been that the requirements, as far as possible, are independent from the selected design. Unfortunately this separation is difficult to achieve in practise because a certain design will always activate or deactivate certain branches of consecutive lower level requirements.

Earlier thinking in connection with systems of requirements was, to a large extent, based on requirements set on the output or product of a certain design process and not at the process itself. This view has changed with the observation that well structured design processes have a larger likelihood of producing high quality products than sloppy design processes. A well structured design process also gives the provision for an early detection of possible flaws in the product. Today it is common to set requirements both on the design process and the outputs it generates.

2.4 The search for acceptable designs

A design process for technical, human and organisational systems can, on a general level, be seen as a search for an acceptable design through an iterative process in which candidate designs are selected, analysed and modified. The first selection of candidate designs is often based on earlier designs that have proved successful. The analysis of a design candidate is undertaken by comparing its predicted performance with applicable requirements. Practical design typically goes through several iterative cycles and the iteration process is stopped when a reasonable, good design has been found.

Another feature of design processes is that they, in the progress of time, move from rather abstract considerations towards more concrete solutions and, at the same time, from a systems view towards subsystems and components (Wahlström et al., 1985). A typical characteristic of design processes is that the freedom in design solutions decreases with time and that the costs of modifications correspondingly increase with time. This tendency is the consequence of the fact that design decisions always build on earlier decisions and that a modification may make it necessary to revoke some of these decisions.

In the search for acceptable designs it is often not enough to conclude that they fulfil a specific set of requirements but it may be necessary to assess the acceptability of the design more generally. This is done by separating between phases of verification and validation, where verification refers to checking that certain individual requirements are fulfilled and validation is used to denote an investigation of acceptability against more general design criteria (Fuld, 1997).

A common goal in the design of nuclear facilities is to achieve a balanced safety profile over different issues. In principle, this implies that marginal improvements in the design will have about the same influence on safety regardless of their target. This kind of Pareto optimality ensures that available resources are spent in the most efficient way.

2.5 The design base and the safety case

The object of design, whether it is a technical, human or organisational system, should be documented as the design proceeds, otherwise important information may be lost. For example, the reason for selecting a specific design may be important in later modifications of the system. The result of the design process should not only be the design itself but also an account of general design philosophy, reasons for selected solutions, reference to calculations, etc. This set of documents is often referred to as the design basis of the plant.

The safety provisions of a nuclear facility are typically documented in what could be called a safety case, which serves as a basis for regulatory licensing. The composition and content of a safety case may vary but it gives a comprehensive account of the safety provisions included in the design. A safety case should, in principle, provide the reasoning from requirements, through design solutions, down to the evidence that requirements are fulfilled. Furthermore, it should provide an integration and interpretation of available evidence to support the argument that the design is acceptable and that no major threats have been left without attention. The safety case is, according to practices today, a living document which is updated to reflect plant modifications. The safety case can be seen as a document by which provisions can be made to ensure that the design integrity of the facility is maintained throughout its lifetime (IAEA, 2003b).

One part of the safety case is the so called safety technical specifications, which define preconditions for safe operation. The safety technical specifications give the basis on which operating procedures are built. The operation of nuclear facilities relies on written instructions. Start-up, shut-down, disturbance and emergency instructions are usually validated using simulators. Operational instructions are typically executed in a step by step fashion to minimise the risk of human error. Administrative instructions are used to give guidance for other work processes. All instructions are reviewed and updated with an agreed interval. Instructions and other documentation are updated after plant modifications to ensure that they reflect the actual plant configuration.

2.6 Feedback of operational experience

The feedback of operational experience is another important part in the safety provisions of nuclear facilities. It relies on the collection and analysis of incidents and accidents to identify weaknesses in the technical, human and organisational systems. The idea is that, proceeding from what happened to why it happened and to why the chain of events was not stopped at some early stage, one can draw conclusions on certain weaknesses and act on them to prevent a recurrence of the incident. In a historical perspective it is evident that incidents and accidents have had a large influence on the development of present safety requirements.

A typical regulatory requirement makes it compulsory to report, analyse and act upon abnormal occurrences at the nuclear facilities. This requirement has also been reflected within the nuclear industry in a world-wide collection, analysis and distribution of lessons from plant incidents. This information is used at the nuclear facilities to identify possible weaknesses in their own systems and the need for modifications.

The feedback of operational experience among the nuclear facilities in the world is further supported by formal programmes implemented by international organisations working in the nuclear field. The WANO peer review programme and the IAEA operational safety review teams (OSART) are examples of such programmes. Similarly, there is an exchange of regulatory experience both at a formal and at an informal level. The feedback of experience serves as a driver for improvements in the technical, human and organisational systems at the nuclear facilities.

2.7 Quality systems

Quality systems can be seen as an organisational system which is used to ensure that work activities are carried out in a repeatable way according to agreed procedures. On a general level, a quality system consists of four parts (Wahlström, 2004). The first part is a description of the quality required in certain work activities and the second part is a description of the methods and tools to be used to reach that quality. The third part is a description of audit and review procedures to be used to ensure that described and actual practices are in compliance with each other and the fourth part contains a description of means to update the quality system.

Quality systems are often associated with the cycle of goal setting, planning, implementation and evaluation, which is aimed at fostering a spiral of continuous improvements. A common trend of today is that the quality system is integrated into a management system to provide a comprehensive approach, not only to nuclear safety but also to labour safety and environmental protection. In this frame it is also used more generally to ensure that instructions and documents are updated, that the impacts of various modifications are assessed before their implementation and so on.

Audits, inspection and review are instruments which aim to detect deficiencies in systems and practices. Such deficiencies may be hidden in the technical, human or organisational systems to influence the course of a sequence of events into unfavourable directions. The analysis of accidents has brought the observation that such deficiencies often have revealed themselves as minor events or weak signals before the accident. This observation carries the lesson of the importance to react also to weak signals of existing deficiencies and minor events.

2.8 Safety management

Safety management has been used as a concept to encompass all activities that are important for safety (IAEA, 1999b). Used in this sense it is important to stress that safety management should not be the responsibility of any single organisational unit but, instead, an activity that permeates all organisational units. On the other hand it is also important to note that certain parts of the technical, human and organisational systems are more important for safety than others. This categorisation is for the technical systems implemented in the safety classification system, which specifies a safety class for each system, subsystem and component. Similar safety classifications for the human and organisational systems are usually not implemented.

One approach in identifying human and organisational systems that have a larger weight in ensuring safety is to talk about systems to ensure competency, systems for strategic and annual planning, decision making systems, risk and safety analysis systems, etc. These systems are used, to a varying extent, by the organisational functions that may, for example, be divided into operations, maintenance and technical support. Another way to trace components of safety management is to map the organisational structure in terms of tasks, authorities and responsibilities. The task of safety management is sometimes seen to be the fostering of a safety culture of the organisation.

Safety management can also be seen to be connected to activities that are used to ensure that all relevant requirements on the technical, human and organisational systems are fulfilled. According to normal quality thinking, this implies that relevant requirements are kept track of and that deviations are reported and analysed to initiate necessary corrective actions. The technical requirements are comprehensive and well known in the operational decision making but requirements on the human and organisational systems are relatively few and are mostly restricted to certain competency and qualification issues.

2.9 Nuclear as compared with other related fields

General considerations of regulation in the nuclear field, as compared with other potentially hazardous industrial fields, suggest some differences. One difference is that nuclear power is considered controversial in many countries, which has led to the emergence of strong political movements against nuclear power. The political controversies have tended to make nuclear regulation stricter and going to a larger degree of detail than in other less controversial areas.

One can also argue that nuclear power is technically different as compared with other means of generating electrical energy. Firstly, the potential hazards are large and obvious. Secondly, nuclear power plants require continuous oversight, even when the reactor has been shut down. Thirdly, accidents and incidents have demonstrated that the complexity of the technology makes it possible that small, seemingly unrelated flaws in design or operation can lead to serious accidents.

All this puts a very strong requirement on nuclear facilities that they should not only be safe but that their operators also should be able to give convincing proof that the facilities actually are safe. This argument is given to a competent regulator that is trusted and has a high integrity. The regulator can then act as a representative for the society with the necessary insight in the technology to, in the first place, be convinced that the plant is safe enough and, in the second place, make that conviction public in statements on construction and operational licenses. For the plants, this scrutiny implies that the plant design, operational principles, management processes, etc. have to be transparent to support regulatory inspection and review.

3 Regulatory practices

Regulatory practices are typically built on a more or less explicit regulatory philosophy. This philosophy is based on historical traditions and it is written into national legislation. It is necessary that nuclear safety regulation is anchored in national legislation because the operation is based on licenses that can be revoked under certain conditions. The regulation in the field of nuclear safety has evolved over many years in response to various forces and, presently, a large diversity can be seen in national approaches. An international view on regulatory oversight has been written into a requirements document by IAEA (2000a). This chapter attempts to provide an overview of different aspects in the regulatory systems to identify where they are similar and where they differ.

3.1 A historical development

There is a considerable diversity in the national practices for regulatory oversight. One reason is that regulatory oversight is anchored in national legal traditions. Another reason is connected to how nuclear power was introduced in a specific country. In many of the large countries, nuclear power plants were built by national vendors and the basis of the regulatory practices was developed in the interactions between plant operators, plant vendors and the regulator. Initially the regulators did not have strong positions, which implied that safety experts involved in the projects both from the vendor and operator sides often, together, agreed on what would be considered as reasonable safety precautions. One may even assume that regulation, in some cases, was used as means of protecting a national nuclear industry.

One important step in developing nuclear regulation occurred when the need for a separation between a promotional and a regulative role was recognised. Another important step in the regulative thinking occurred when some smaller countries imported nuclear power plants from different major vendors and were placed in the situation of integrating the regulatory systems according to where these plants were designed, constructed and operated. A third step in rethinking regulatory strategies in Europe was taken when the political processes led to the establishment of new regulatory bodies in the former eastern countries. IAEA has played a major role, both in the development of the reasoning about nuclear safety and in the development of regulatory competency in various countries. Today a shrinking number of vendors has increased the need for an increased harmonisation between the regulatory systems.

3.2 Components of regulatory oversight

Regulatory oversight can be seen as the final step in the safety precautions of nuclear facilities. It ensures that there is an external independent body that acts as an agent for the society in ensuring that the facilities can be operated with sufficient safety. Regulatory oversight has three basic functions (IAEA, 2003a):

- to develop and enact a set of appropriate, comprehensive and sound regulations
- to confirm compliance with such regulations
- in the event of a departure from licensing conditions, malpractice or other wrongdoing enforce the established regulations by imposing appropriate corrective measures.

Independence is one of the key features of regulatory oversight. This independence is necessary to offset bias and conflicts of interest to give the regulator ability to speak up and act in any occasion of concern. The regulatory oversight should be based on professional dialogues and consultation, with both licensees and third party experts. Regulatory decisions should be based on science and technology. Any judgements should be based on relevant experience, which is accompanied by clear explanations of the underpinning reasoning. It is important that regulatory oversight is consistent and predictable, with an appropriate relationship to safety objectives as well as to legal and technical criteria. This implies that regulatory actions should be transparent and traceable, which again sets requirements on documentation and archiving. Finally, a regulatory body should have a continuing dialogue with representatives for the society, such as politicians and state officials, along with appropriate mechanisms for dialogue with the public to ensure that the regulatory oversight is in line with societal goals and preferences.

3.3 The basis for regulatory oversight

A common basis for nuclear regulation is that an absolute and undividable responsibility for the safety of a nuclear facility lies on the holder of the license. This means that actions of the regulator cannot inflict on this responsibility. The regulatory responsibilities are, thus, restricted along with those of civil servants, who have to be impartial and just with a high integrity to act at any malpractice they may identify.

This general principle implies that the regulator should never interfere with decisions made by the licensees. The regulator should, instead, define the borders of acceptability and let the licensees select their own solutions within that frame. If the borders of acceptability are crossed it is the responsibility of the regulator to impose appropriate sanctions. The difficulty with this general principle is to define the borders of acceptability. In a discussion of regulatory oversight, fears have sometimes been expressed that a prescriptive and detailed definition of these borders may move the responsibility for the solutions from the licensee to the regulator.

The regulatory mission and tasks are typically written into high level national legislation. Legislation at lower levels is, in some countries, giving rather detailed technical requirements to be fulfilled whereas, in other countries, similar requirements are issued as guidelines. There seem to be differences between regulators in how they view their own mission. Some regulators see their mission as being to work actively for continuous improvements of safety over time, while others have a more passive, compliance based approach.

The position of the regulatory body within the national administrations varies. It may be truly independent but, in most countries, it is in the national administration connected to some of the ministries such as environment, social affairs, industry, etc.

There is a large international consensus that the regulator should be independent. This independence is easy to achieve on paper but it may be more difficult to ensure a real independence. Independence implies, for example, that necessary funds and resources are available for building up and maintaining necessary regulatory competency and skills. Regulators in some countries seem, for example, due to historical reasons to be better equipped than regulators in other countries. The existence of a national technical support organisation (TSO) may also influence the basis of regulatory oversight. There seem to be slight variations from country to country in the interpretation of what this independence implies in practical terms.

The Convention on Nuclear Safety that entered into force in 1996 can be considered a remarkable step in bringing more transparency into the legislation and regulation on nuclear power (IAEA, 1994). The national reports that have been published under the obligations of the Convention are very informative and have been important in discussing and comparing national approaches.

3.4 Regulatory strategies

In a consideration of national systems for regulatory oversight one can observe a large diversity in applied strategies. A recent report, which is based on interviews with representatives from the regulatory bodies in six countries, gives one overview of regulatory strategies (Melber and Durbin, 2004). The report identifies six generic strategies, (i.e. prescriptive, case based, outcome based, risk based, process/system based and self-assessment based) and it uses this division to discuss regulatory ruling in specific cases. When these cases are assessed it is evident that a mix of these strategies is usual in practical cases of regulatory ruling.

A slightly different way of considering regulatory strategies is to identify dimensions that, in some sense, can characterise a conscious placement of a specific regulatory approach. In addition it is important to recognise that the term 'prescriptive' may not be a correct characterisation of a strategy because some requirements in a regulatory system may be compulsory, others may be guidelines and still others a collection of good practices. Based on these considerations the following dimensions could be suggested:

- general – detailed (a dimension characterising the level of detail of the requirements in the regulatory system)
- case – rule based (a dimension characterising if the safety argumentation is built as a single case or in compliance with a certain set of generic rules)
- deterministic – probabilistic (a dimension characterising the relative weight, which is laid either on deterministic or probabilistic safety arguments)
- performance – process based (a dimension characterising the relative weight, which is laid either on assessing the output of used work processes or their internal structure and control)
- level of involvement by the regulatory body (a dimension characterising the relative weight, which the regulator is placing on own oversight as compared with oversight of the self-regulative functions of the licensees).

In a characterisation of, for example, differences between the regulatory systems in the US and the UK, one may say that the US system is rather detailed and rule based, whereas the UK system is more general and case based. Furthermore, a comparison of the Finnish and the Swedish regulatory systems would suggest that the Finnish system is more detailed than the Swedish system and that it, to a larger extent, relies on actual involvement of the regulator in inspection and review activities.

All regulatory systems today seem to move from a mostly deterministic approach to the inclusion of an increasing amount of probabilistic reasoning. Similarly, there is a general trend towards using more process based arguments in the regulatory ruling. These trends seem, however, to be more connected to a change in views of how safety is constructed than to any specific regulatory strategy.

One can argue at length on the relative merits of specific orientations in the regulatory oversight but the important point is to understand how specific positions can influence the resources needed and the interactions between the regulator and the licensee. A detailed system of requirements can be demanding of resources in its development and maintenance but it can give better guidance in regulatory inspections. A case-based system is flexible but it may introduce more difficulties in ensuring consistency in regulatory ruling. A large involvement in inspections and reviews is demanding of resources but it makes it easier to maintain regulatory competency. The final selection of which strategies to apply will always depend on regulatory ambitions and traditions.

3.5 Regulatory requirements and guidelines

Regulatory requirements and guidelines are developed in response to selected regulatory strategies. They can be given an internal structure to support inspections and review during different phases of the life cycle of a nuclear power plant. They typically set at least some requirements on all of the three major systems, i.e. the technical, human and organisational systems. For the more detailed ruling they often give reference to applicable norms and standards. The requirements are usually formulated, on a functional level, by defining certain functions that should be found and the quality requirements these functions should fulfil.

One important feature in the regulatory requirements is that they require the identification of functions, systems and equipment that are important for safety and a classification of this importance. This classification is connected to the deterministic safety approach, which presumes certain oversight procedures to be connected to specific safety classes. The safety classification serves as shorthand in the allocation of work efforts and in the use of certain methods and tools in the verification and validation. With the introduction of probabilistic approaches the safety classifications have sometimes been questioned but, currently, there seems to be a consensus that the safety classification is needed and that it actually can be supported by probabilistic arguments.

A system of regulatory requirements and guidelines can provide a large support for design and operation as well as for regulatory inspection and review. To serve this purpose it has to be described in writing and it should be continuously updated to reflect new operational experience. A well written and maintained system of requirements can be of great help in ensuring objectivity, transparency and fairness in regulatory ruling. On the other hand, a detailed system of requirements can be rather demanding of resources and it may stifle innovation. Again, the solution selected regarding the system of requirements will depend on regulatory ambitions and traditions.

3.6 The safety analysis report

The safety analysis report (SAR) has an important position in regulatory oversight. In some countries the concept of a safety case contains the essential components of the SAR. A SAR collects, in principle, the full documentation of how safety is built into design and operation. The SAR is typically required when the licensee is applying for an operations license, which can be granted upon approval of the SAR. A common requirement is to keep the SAR as a living document, which means that it should be updated to its relevant parts when modifications to plant systems are made.

Regulatory handling of the SAR will always include the delivery of certain documents from the licensee to the regulator. It is important that the time schedule for these deliveries is in synchronisation with the progress of design and construction, not to introduce undue hurdles by a requirement to submit documentation, which will emerge only later in the process. The two processes of design and licensing should be interfaced in a reasonable way, from initiation to the end, to ensure that the licensing process can proceed in a smooth manner. To reach this goal in practice it may be necessary for the plants to have early discussions with the regulator on how to build the interfaces and when certain documents can be expected to be available.

The SAR can also serve as a basis for regulatory inspections and review, for example, in assessing the acceptance of plant modifications. The main principle applied is, in this case, that modifications that will change the SAR have to be based on a regulatory approval.

3.7 Inspections, reviews and other oversight activities

Inspections and reviews are instruments with which the regulatory body confirms that requirements are fulfilled over the life-cycle of a nuclear facility. Inspection and review can be based on physical inspections of systems and components, on observation of work practices, on document reviews and on interviews with various groups of people. Inspection and reviews can be carried out both broadly, by assessing several related activities and deeply, in going down to great detail in the arguments for safety. Inspections and reviews could be based on an assessment of all issues selected by a certain criteria, on a sample of issues in this selection or by assessing the efficiency of the self-assessment of the licensee for these issues. When regulatory inspections and reviews are carried out in practice, they are often targeted to some selected functional area, organisational units, work processes, etc. Sometimes, so called systems inspections are carried out, which means that they are targeted specially on interfaces between various entities.

Inspection and review implies that there is some norm against which observations can be compared. If there is a comprehensive system of requirements this comparison is easy. A typical practice in inspections is to classify the observations that are made on a scale of importance. This means, for example, that some observations are classified as deviations to stress their seriousness. If an observation is classified as a deviation, it is usual to require that it should be corrected within a specified period of time. A typical regulatory approach is to follow up deviations and observations half a year or a year after the inspection.

Inspection and review is typically planned, in part, as a regular programme and, in part, as an event based programme. The regular programme is typically rotating to ensure that all relevant activities are inspected at selected intervals. Event based inspections are typically related to some specific regulatory concern that may have been revealed in connection to some incidents at the nuclear facility. Most of the inspections are initiated after a notification to the licensee of areas to be inspected. A usual practice is also that a few inspections are made without prior notification. The planning of inspection programmes is usually made with some kind of risk consideration to target them to issues that are important for safety. Most national regulation includes requirements to carry out periodic safety reviews with an interval of about ten years. In some countries the renewal of the operational license provides a natural frame for these periodic safety reviews.

3.8 Use of performance indicators

Indicators have been proposed to be used to monitor the safety performance of nuclear facilities (IAEA, 2000b). In this spirit some nuclear regulators have introduced safety performance indicators to support the information provided by inspections and review in giving an overall assessment of the safety of the facilities operated by their licensees. There are certain difficulties in the use of indicators but, if these difficulties are understood, the use of safety performance indicators can provide valuable support for regulatory oversight (Wahlström, 2002).

The selection of indicators is typically based partly on issues that are assumed to have an influence on nuclear safety and partly on the availability of objective measurements that have a relation to safety. For example, the unavailability of safety systems, the number of incidents, the number of exemptions from the safety technical specification, radiation doses, etc. are typical indicators that have been used. Similarly long backlogs in applying recommendations from internal audits or analysis of incidents carry a message of slippages in important safety related activities.

3.9 Regulatory enforcement

Whenever a non-compliance with some requirement is detected there is a call for actions of enforcement from the regulator. Depending on the seriousness of the deviation, the actions could range from asking for additional explanations and a plan for how the deviation will be corrected, all the way to a regulatory letter in which the operating license is revoked with immediate effect. There are countries where detected non-compliance in some cases has led to criminal prosecution and fines. In these cases the offence has usually been considered flagrant or deliberate.

It is an important principle that regulatory enforcement is placed in relation to the seriousness of observed deviations. A revocation of the operational license with immediate effect can, for example, be considered as motivated in the case of an assumed or identified deficiency in some of the major safety precautions that are built into the plant. If only some minor safety related feature of the plant is found to be deficient a suitable policy may be to allow operation to the next planned outage of the plant. These regulatory decisions are always difficult to make because they usually involve engineering judgement. In some cases it may be necessary to have a common discussion session between the regulator and the plant to find a reasonable strategy for the correction of identified deficiencies.

3.10 Development of the regulatory system

A regulatory system should be developed continuously to reflect the accumulation of operational experience and new knowledge from research. This has been the case, which can be seen in considering the development of nuclear regulation since the early introduction of commercial nuclear power plants for electricity generation. In this development, accidents and incidents have played an important role in pointing out deficiencies in earlier approaches. One example is the development of requirements in coping with severe accidents, which were introduced after the TMI accident. Another example is the requirements concerning safety culture that have their origin in the Chernobyl accident.

Over the years many new requirements have been brought into the regulatory system, new areas of regulatory oversight have been included and there have been new principles in dividing work between the regulator and third parties, for example when expert judgements and independent assessment organisations have been employed to support regulatory oversight. The deregulation of the electricity market has also brought changes into the practices of regulatory oversight.

When a new regulation is introduced, there is always the question of how this regulation should be applied to the old facilities. In case a new regulation has been developed to cope with some major deficiencies, a reasonable approach is to require that the new regulation should be applied also for the old facilities, perhaps with the provision of a suitable transition period. In other cases it may be more natural to apply the new regulation only for new plants because it can be very expensive to comply with the new requirements and it may, therefore, be more reasonable to allocate the spending on safety improvements in a different way. In other cases old nuclear power plants have been upgraded to a higher rated power output as compared with their original operating license. Such modernisations usually require extensive modifications and a renewal of the safety case. In these cases a natural approach may be to require that the new design should be licensed according to the new requirements.

3.11 Regulatory performance

To improve regulatory practices it is important to build in systems for performance evaluation into the regulatory practices. One may, for example, distinguish between the concepts of regulatory effectiveness to mean doing the right things and regulatory efficiency to mean doing things right (OECD/NEA, 2001a). The internal management and quality system used by the regulator should, for example, include regular performance reviews. Suggestions for such reviews include the use of performance indicators to assess the regulatory processes (OECD/NEA, 2004). National regulators also have an administrative position within the public services, which implies that the regulatory activities are controlled through planning and resource allocations. It is a good practice that the licensees are given the opportunity to provide their views on the regulatory system and performance.

To understand the pressures that are put on regulatory performance it is necessary to consider all stakeholders in the regulatory activities. These are governmental bodies, the licensees, other regulators and international organisations but also media representatives and the general public. Some regulators have, through questionnaires or other types of surveys, tried to assess the confidence and trust that they get from the general public. To support the development of regulatory performance IAEA has instituted so called international regulatory review teams (IRRT), which conduct peer review missions (IAEA, 2002a).

Performance is always a function of available resources. In some countries the regulatory body is funded by governmental allocations and in other countries the regulatory body is supposed to collect the funds from the licensees in the form of service fees. The funding arrangement may have an impact on how the regulatory body is viewed by its licensees. In the case of shortage in available funds the regulator may be forced to allocate available resources in accordance with cost benefit considerations.

4 Regulatory challenges

There are many challenges connected to the regulatory mission. Some of these challenges are due to the division of roles between the regulator and the licensee, whereas other challenges are more generic and connected to problems of finding a good balance between organisational goals. These challenges are reflected in the difficulties of finding organisational structures to carry out the regulatory oversight that reflect all goals and requirements. These difficulties dissipate as stressors to the day-to-day oversight practices and dialogues between inspectors and their counterparts at the nuclear facilities. This chapter discusses some of these challenges and the solutions that have been selected in approaching them.

4.1 Organisation and management

The importance of organisation and management as a precursor to performance and efficiency has been recognised broadly within the nuclear field over the last couple of years. A recent IAEA document brings forward many good principles of organisation and management as applied on the regulatory oversight (IAEA, 1999c). The guidance given in the document is, to a large extent, in line with similar guidance for efficient structures of organisation and management as given more generally.

There may also be internal challenges to achieving key features of regulatory decision making. Such challenges may initiate the need for specific organisational development efforts such as, for example:

- a development of clearly defined safety objectives and criteria, to make it easier to achieve consistency and predictability in regulatory decision making
- competence development programmes to ensure that regulatory decisions are firmly based on science, proven technology and relevant experience

- the institution of succession planning and knowledge transfer programmes to decrease the vulnerability of the regulator for the retiring of key senior managers or inspectors
- the creation of clearly defined procedures and criteria for the appointment and promotion of staff to managerial and decision making positions in the regulatory body.

4.2 Oversight without involvement in plant decision making

The separation between the two roles, the role of the regulator and the role of the licensee, represents a large challenge in itself. It implies, for example, that all influences from the regulator towards the licensee have to be indirect. Comments should be given on conditions that do not fulfil requirements but it is always the task of the licensee to find the remedies. Failures in the separation of these two roles can be seen on both sides, for example when the regulator suggests a solution or the licensee asks for one. This division of roles can be seen as an invisible border that should not be crossed by either of the two parties.

The regulatory oversight includes the threat for the licensee that deviations are detected, which may introduce a tension in the communication and even hiding of information. The communication between the regulator and the licensee also requires a certain degree of formality to ensure that decisions and actions are possible to trace afterwards. Regulatory inspectors should be sensitised to the importance of the two roles but putting too high emphasis on them may distort the common goal of a safe facility.

4.3 Definition of acceptability

The definition of acceptability is a reiteration of the question of what is safe enough. On the one hand, it is important to have clear criteria for acceptability but, on the other hand, the answer will always depend on specific conditions. Very often this question can only be resolved by weighing together a large number of views which are based on engineering judgement. Sometimes a resolution can be obtained by comparisons of what can be considered as normal engineering practices and what can be considered as the best available technologies.

The acceptability issue is also connected to the completeness of safety considerations. If sound arguments are presented to prove that all relevant threats have been addressed and that the presented solution is robust, it is easier to consider it to be acceptable. Sometimes it is necessary to assess costs and benefits of a certain solution and compare them with costs and benefits for some other solution to determine their relative merits. Resolutions for such comparisons have, often, to be based on a probabilistic reasoning. Attempts have been made to use comparisons with other societal decisions in using risk analysis to calculate the value of human life in similar situations. These calculations can provide some guidance but their societal acceptance has been low.

It is not likely that absolute and lasting norms for acceptability will be found. A practical approach may be to define what certainly can be considered acceptable and what certainly can not, to leave a grey zone for negotiations. Therefore, it is important that a continuing dialogue takes place between the regulatory body and stakeholders in the regulatory actions to ensure that criteria for acceptability continuously are renegotiated and updated.

4.4 Regulatory ruling and decision making

Regulatory ruling and decision making are sensitive issues in the interface between the regulator and the licensees because they are bound to introduce burdens in terms of costs and additional work. The threat of a revocation of the operational license can also, in one moment, redirect all efforts of the whole organisation to tasks that were not originally foreseen. It is evident that such abrupt changes in the operational focus may have an impact on safety.

Regulatory ruling and decision making has to be transparent and well underpinned with undisputable arguments. This means that large interventions should not be initiated on beliefs and feelings only. On the other hand, it is important that regulatory interventions are not delayed unnecessarily, especially in cases when the situation is expected to shift from bad to worse. It may also be necessary to make pre-empting moves to ensure that an upcoming intervention is handled in an appropriate way. Due to the burden an intervention puts on the licensee, it may sometimes be reasonable to start with a relatively modest regulatory reaction if the deviation is known and already acted upon by the licensee. On the other hand, a modest reaction may confirm a wrong assumption by the licensee that the situation is under control.

Regulatory decision making involves several such balances, where regulatory response has to be adapted to the seriousness of the detected deviation. For example, a balance between firmness and flexibility may involve weighing the need for taking a relatively minor deviation as a lesson to others against a more understanding reaction. Interventions should be based on sound evidence that there is a deviation but, if the collection of convincing evidence takes time, the intervention may come too late.

4.5 Setting principles of regulatory oversight

It is never an easy task to set general principles for regulatory oversight. It implies a manoeuvring between pros and cons of different strategies and solutions. There are many drivers that affect views on how regulatory oversight should be structured. The first, and most important, is the view on how safety is constructed. Over the last couple of years the search for a proper balance between deterministic and probabilistic approaches has introduced a move towards risk informed regulation. A second driver is the recognition that prescriptive regulation has many drawbacks which, again, has suggested that performance based regulation would be a better way to structure requirements and inspection practices.

Other drivers are connected to more general views in the society on how work should be organised for efficiency. There is one clear tend towards networking between organisations and to using services on a global market. This trend will, most likely, also influence nuclear regulators, although the actual influence of this trend so far has been small. Another trend is to use flatter organisations and to use empowerment to increase motivation within the personnel. This development fits well into the experts' organisation, which most regulators are. Such a development has, however, also shown the importance of training people in initiative and responsibility.

One can see a trend in society, where an authority is not seen, as previously, as bureaucrats or polices but as public servants in a specialised function. This change in societal views on the regulatory role may also introduce corresponding adaptations in the regulatory system.

4.6 Integrating new knowledge in the regulatory system

It is very clear that new experience and knowledge should be integrated into the regulatory system as a continuing effort. This includes findings from both operational experience and new research. The important question is how these findings should be integrated into the regulatory system and when the modifications should be implemented. A regulatory system should be stable and, therefore, it is beneficial that it has a hierarchical structure, where small changes can be brought in more rapidly on the lower levels. Radically new findings may require a rapid integration also on higher levels, which means that such preparedness should be found. When new findings are to be integrated in the regulatory system it is important that the licensees are informed and can prepare themselves in good time for the changes.

Another challenge is to update the documentation of the regulatory system. Already, finding the places in the documentation which have to be changed can be a large task. It is also necessary to ensure that modifications do not bring in new inconsistencies. In the mean time, it may be necessary to live with two systems in parallel. A regulatory system that comprises hundreds of pages has to be updated gradually, which means that it is likely that there will be, at least occasionally, internal inconsistencies between different parts. The final challenge is that, at some point in time, it may be necessary to rebuild the whole documentation to tidy up after a long period of patch and mend in the system.

4.7 Maintaining regulatory skills and competency

The challenge in maintaining regulatory skills can be captured in the challenge of creating an understanding without doing. Inspection and review of nuclear facilities requires a thorough knowledge and understanding of the content of work and how it actually is done at the nuclear power plants. This knowledge and understanding is typically acquired by designers and operators in doing their job but this source is closed for regulatory inspectors. One possibility would be to hire inspectors from the industry but, at least in some countries, this is considered as a threat to their independence.

One possibility is to rely on outside help for demanding inspection and review tasks and many regulators actually have so called technical support organisations (TSO) that can be used for various specialised skills. This solution can help but it carries its own problems because an outside organisation can only supply expert opinions, which have to be understood and weighed against other evidence in a decision making process. Outsourcing of technically demanding tasks may also influence the regulatory organisation negatively by not allowing the inspectors take on intellectually challenging tasks.

There are many technically orietanted skills and competencies that are necessary in the inspection of design and operation. In addition, there are also many human and organisational skills that are necessary for a smooth execution of regulatory tasks.

Firstly, inspectors should have a high personal integrity and a respect for ethical principles and codes of conduct. They should have a good knowledge of the legal framework of nuclear power and a sufficient understanding of the different ways in which the work can be organised at the nuclear power plants.

4.8 New areas of regulatory competency

In a quarter of a century many new areas have been brought in where regulatory competency is needed. For example, the TMI accident brought the insight that human factors can have an important influence on safety. This insight has been responded to by issuing guidance on control room design, operating procedures and operator training. Similarly, the Chernobyl accident placed a focus on safety culture that has not yet got its complete resolution within the regulatory systems.

Lately, there has been a growing regulatory interest in issues connected to leadership and management, which is due to their apparent influence of organisational factors on safety. Today there is still very little guidance in this area on how to set requirements and to inspect that they are fulfilled. Plant economics has also attracted regulatory interest by the recognition that the allocation of resources to different activities at the facilities can have important impacts on safety. An additional difficulty in handling these areas is that it becomes easy to endanger the separation of the regulatory and licensee roles.

Digital I&C is a new technical area, which has caused a large amount of discussions on how to set the requirements and how to verify that they are fulfilled. It has become very clear, especially for the programmable I&C systems, that it is not enough to set requirements on the product but also on the processes by which it has been produced. For a new technical area one would expect that similar regulatory approaches would have been developed but this does not seem to be the case in a consideration of national practices (Wood et al., 2004).

4.9 Changes in regulatory philosophy

At some point in time, different changes in any organisation may add up to a point when there is a need to introduce new thinking. Such changes can be painful for organisations and they typically create a large amount of internal controversy. It seems that some regulators have gone through this kind of rather profound change. The present move from prescriptive to risk informed and performance based regulation seems to show some characteristics of such a radical change.

Another change in thinking is connected to the proposals for the separation of the roles of defining requirements and inspecting that these requirements are fulfilled. Such a change has been implemented in other regulatory regimes and the question may come up also within nuclear safety for two reasons. Firstly, there are strong drivers in the society that as many areas as possible should be opened up for competition. Secondly, an agency which has a monopoly should not be able to generate work for itself. It is not likely that such a change will be introduced in the nuclear field in a short term but an increased harmonisation of different regulatory regimes and a continuing globalisation may open up for such a change.

4.10 Effectiveness of regulatory oversight

The final challenge in regulatory oversight is to assess its effectiveness. The difficulty is to find appropriate criteria for judging effectiveness, which evidently should not be based on how many new requirements have been enforced or how many deviations from the requirements have been found. To base the criteria on actual safety performance of the nuclear facilities would be one possibility but the main credit for these achievements should still be given to the licensees. There has been some guidance on how to approach these problems but the guidance is directed more towards good practices of organisation and management (IAEA, 1999a; OECD/NEA, 2001c).

It is clear that a discussion of regulatory effectiveness in some form or another should bring up all the issues that have been touched on in this chapter. It may not be possible to build indicators for regulatory performance but it may help to, at regular intervals, try to answer the question of what the major indicators of regulatory performance could be. It may also be of help to consider a small set of balances and ask if the balances have been set right in decisions and actions. Such a set of balances may consist, for example, of the following issues:

- operational versus strategic (is there a proper balance between short and long term activities)
- overreacting versus under-reacting (has the regulatory intervention been properly balanced in view of observed deficiencies)
- stability versus innovation (are the regulatory systems reasonable stable but still allowing for innovations)
- firmness versus flexibility (have the regulatory decisions been firm but still allowed room for adaptations of the licensee)
- standardisation versus pluralism (standardisation of practices between areas and licensees can save resources and reduce errors but pluralism is needed to ensure that nothing important has been forgotten).

A final question in evaluating the effectiveness of regulatory oversight is connected to the use of resources. A larger allocation of resources always will allow more to be done but the question is if some reallocation would make it possible to reach a higher safety of the nuclear facilities. This consideration should also look at the allocation of resources between regulator and licensee because this can, in a societal context, be seen as a zero sum game. In this connection it is important to note that the amount of resources spent on inspection and review always will depend on the trust and confidence in the interactions between the regulator and the licensee.

5 Complaints on regulatory oversight

Regulatory oversight always has its times when the licensees find regulatory actions awkward and badly timed. In assessing such complaints it is important to accept that they have causes that may be on either side of the two parties. It is very clear that regulatory oversight is intended to challenge the licensee to find safe and economic solutions to the various problems that may emerge. On the other hand, regulatory oversight has to be carried out in a considerate way so as not to infringe on the division of roles and responsibilities. The following chapter discusses some of the most usual complaints that have been heard on regulatory actions from the licensees.

5.1 The regulatory role

The two roles of the regulator and the licensee have been shown to create, if not direct, controversies but at least discussions. Most senior managers in the licensee organisations can give examples where the regulator has come near to the invisible border of interfering with decisions to be made by the licensee. On the other hand, it is equally often that representatives for the licensees ask the question ‘if that is not acceptable, then please tell us what would be’. A resolution of this problem could be to sensitise both regulatory and licensee managers to the implications of the two roles.

The regulatory bodies have the dual task of developing regulation and inspecting that the requirements are fulfilled. These two roles may cause a conflict because one may argue that it would be in the interest of the regulator to create a complicated system of requirements to ensure a continued work load in inspection activities. Similarly, one could argue that it is not in the interest of a regulator to participate in activities that aim towards a harmonisation of the regulatory systems because the national regulation is important for regulatory employment.

Regulatory bodies typically obtain funds for research either through public sources or through funds collected from the industry. This research is often targeted to support regulatory oversight, which may create tensions between regulatory and industrial research. In some countries the regulatory research is carried out by technical support organisations (TSO) and in other countries mainly by the universities. If these organisations are funded only from one source it may, in the long run, have a negative influence on the direction of the research and the credibility of the results.

5.2 The regulatory system

There are many complaints from the nuclear industry on prescriptive regulatory systems. This critique is well founded but a part of the critique may have been avoided with a policy of a more proactive development of the systems of requirements. Over the years the systems have become heavy and their internal structure has become blurred. It has also been difficult to remove outdated requirements from the systems.

The regulatory system should be transparent, which may require some pedagogical documents to support an understanding of the general philosophy, regulatory mission, role, vision, objectives, etc. Furthermore, the regulatory requirements should be given a logical structure, the requirements should be balanced and they should not be in contradiction with each other. Requirements should also be consistent in their use of concepts and terminology. Requirements are written in natural language and they are therefore sensitive for interpretations. When interpretation occurs it is important that they are reasonably stable over time. Whenever possible, the regulatory requirements should be in reasonable harmony with international practices.

It is important for the transparency of regulatory decision processes that all regulatory decisions are accurately documented and communicated. It is also important that regulation is updated at regular instants to reflect new operational experience. Some regulators have selected to make their regulation more easily accessible by providing computerised versions, which allow for efficient search procedures. Computer support can also give certain advantages in ensuring that consequences of changes in the regulation are properly reflected.

In the beginning, when nuclear power was introduced, one important pioneering activity was to institute the norms and standards that had to be applied to the new technology. In that time the standards used by the conventional industry were not satisfactory for the demands of the nuclear industry. This situation has changed considerably and today there are standard high-quality products that actually may be as good as and sometimes even better than products designed with the nuclear industry in mind. It is evident that the nuclear industry will only suffer in the case of over-regulation in areas which may be handled satisfactorily using normal industrial standards.

The nuclear industry is often claimed to be conservative. One reason for this conservativeness is the requirement that only proven technology should be used. It is clear that certain cautions should be applied in introducing new technologies but erecting barriers against a prudent utilisation of new innovations can only hurt the nuclear field. Too much conservativeness in regulation would practically freeze all development at the nuclear utilities.

5.3 Targeting interventions

Regulatory interventions always place an additional burden on the licensee. Interventions may range from issuing questions on some minor detail to involving forcing some major improvement in plant design at a rapid time schedule. For most of the interventions there is no difference in opinion on the need for the intervention but sometimes the licensee opinion is that the intervention is out of proportion or that it would divert utility attention and resources from more urgent safety issues.

Interventions should always be handled case by case with the provision that a certain base intervention can be either strengthened or loosened based on the actual situation. If, for example, an issue has been identified in an inspection and the licensee has already acted on it, a prudent approach may be to recognise this fact and adapt the intervention accordingly. If, on the other hand, there is a new issue that adds to a row of other unresolved issues, it may be prudent to make a more forceful intervention. In both cases it would, however, be important to make the case clear with a statement on what would be a normal way to intervene in the case in consideration.

5.4 The need for formality

In the nuclear industry there is a need for a rather high level of formality due to different reasons. However, it is also important not to require formality just for the sake of it. One such example could be to enforce a correction of all spelling errors in a certain document before it can be approved. The difficulty here is that there always will be some grey zone between cases in which the ruling is obvious.

One approach in meeting this complaint could be to initiate systematic efforts to agree on a proper level of formality which takes into account the need for a proper documentation in all phases of design and operation. Such needs are, for example, connected to certain instructions and the recording of events and actions. A strict following of operational instructions is, for example, important to avoid simple slips of mind and the recording of actions to ensure traceability and repeatability. If such changes in the view on formality can be introduced, they would be implemented through the quality systems.

The interfaces between the regulator and the licensee also require some degree of formality which, sometimes, may feel unnecessary and stifling. An open dialogue between the regulator and the licensee may, however, help in resolving these issues.

5.5 Lack of regulatory flexibility

Complaints on the lack of regulatory flexibility are often heard at the nuclear facilities. Actual cases of such controversies often arise in the interpretation of certain requirements. Requirements written in normal language unfortunately often leave room for interpretations and it may, therefore, be important to document also the intent of the requirements. Sometimes a specific requirement may actually be outdated due to changes in the regulatory system or due to changes in used technologies.

If the regulator on some specific requirement takes a position which is very literal without a consideration for the actual impact on safety, this can create a heated discussion. Practical cases have, sometimes, to do with the regulatory handling of exemptions from the safety technical specification, the approval of certain design solutions or agreeing on a result from PSA analysis. A part of these may actually be a controversy between deterministic and probabilistic approaches in reasoning about the acceptability of a certain solution. In such cases, the involvement of both disciplines may help in resolving the issue, the credit to be given either to the deterministic or probabilistic arguments.

Sometimes a lack of flexibility may be traced to an individual uncertainty and unwillingness to take responsibility. It is always easy to hide behind a literal interpretation of requirements, instead of going deeper into the arguments. The only way to combat such behaviour is training in a systemic view on how different issues influence safety combined with a support of personal initiative and integrity.

Controversies sometime arise concerning the time which is allotted to the licensees for certain actions to be completed. A similar controversy arises from the timing of the submission of certain documents. The actual problem connected to these complaints may, however, often be on the side of the industry because some licensees seem always to be late in their submissions or to be submitting incomplete material.

5.6 Restricted industrial experience

A usual complaint by the industry is that the regulator has a restricted industrial experience. Ideally, the regulator should have a very good understanding of the industry and the conditions in which it operates because such an experience can help in targeting regulatory oversight to important areas and in making the communication between the regulator and the licensee easier. Unfortunately there are hurdles, which may make this good intent difficult to achieve. One hurdle is connected to the independence of regulatory decision making because some regulatory agencies, for example, avoid hiring persons from the nuclear utilities, where others actually see the opposite policy as more beneficial.

It is important to observe that regulatory oversight is a different matter from designing and operating nuclear facilities. A regulator has to master special fields in line with their mission and role. They can also have a deep theoretical insight in some specific technical, human or organisational systems that will enable them to see possible threats from a different point of view. If the regulator has the ability to act as a competent discussion partner in safety matters that challenges the nuclear plant to present even safer solutions in plant design and operation, this will always be respected.

5.7 Hoisting of safety requirements

In some regulatory regimes there have been periods with a rapid evolvement of new regulations. This may take place, for example, after some spectacular event or during a rapid evolvement of new technology. During such periods the impression of the industry has sometimes been that national regulators are overbidding each other in developing the most stringent systems of requirements. Periods of rapid development of new requirements may bring the industry to a situation where no good solution of compliance can be found. There is also a danger with very detailed and prescriptive systems that a simple importing of some requirement from another regulatory system may introduce inconsistencies and contradictions. Some complaints have also been made on the practice of rapidly integrating safety innovations originating from the licensees as prescriptive requirements in the regulatory systems.

If the time given to the licensees to comply with new regulation is very short, it may prevent a search for good and sustainable solutions. On the other hand, if the time is too long it may cause a lax attitude to the need for adapting to the new requirements.

It is important that the industry accepts the legitimacy of an introduction of new safety requirements because the real challenge for safety in the nuclear industry is to correct deficiencies before they become obvious in an accident. This means that a simple argument that something has never proved to be a problem before can not be accepted as such. Instead, suggestions for stricter safety norms in any system should be approach with prudence and vigour.

5.8 Regulatory control of outsourcing and the use of contractors

Recent regulatory concern has been directed towards outsourcing and the use of contractors. From an outsider's point of view, it is clear that both practices have both benefits and dangers. However, if these organisational changes are handled in a proper way, they should be able to contribute to a higher efficiency without introducing new threats for safety. Outsourcing, for example, could improve the exchange of good experience between the nuclear and conventional industries but it, evidently, also carries the risk of losing competencies. This issue is connected to the decision to produce or to buy which, evidently, should be made by the licensee. A proper approach to this decision is to identify core competencies and develop strategic plans for competencies required over the life cycle of the plant (Wahlström et al., 2005).

Nuclear facilities use contractors in the support of operation and in plant modifications. It is clear that the use of contractors implies that the licensee takes the same responsibility for work that has been contracted out as for work done by its own personnel. This implies a considerate screening of possible contractors, a careful selection of contractors for different tasks, detailed description of the work to be done and a careful supervision of the work the contractors do (IAEA, 2001). There are differences in national approaches in how regulators approach the use of contractors (IAEA, 2000c). In some countries contractors and suppliers are not licensed by the regulator provided that they meet agreed criteria. In other countries regulatory bodies have a legal mandate to exercise direct control over contractors and subcontractors, which may involve the application of licenses, authorisations, accreditations or re-qualification for specific work.

In considering this issue from a regulatory point of view, the only durable approach seems to be to ask for evidence by the licensee that certain dangers have been identified and reacted on. If the licensee takes the full responsibility for the quality of outsourced or contracted work there should not be any objections. Also, an approach where the regulator actually exercises a mandate of direct control of contractors and subcontractors seems to be consuming resources without a real contribution to safety.

5.9 Regulatory interest in plant economics

The typical regulatory standpoint used to be that they had no interest in economic performance but only in issues connected to safety. This approach has changed with the recognition that a strained economic situation may tempt licensees to take shortcuts in the oversight of safety. The deregulation of the electricity market has, therefore, introduced additional regulatory concerns (OECD/NEA, 2001b).

Economics and safety are intertwined because only a safe plant can be economic. The pursuit of availability will often spill over to safety because a smooth operation without disturbances is beneficial also for the safety of the plant. However, the regulatory interest in plant economics carries a risk of infringement with the responsibility of the licensee. It is, for example, very clear that the processes of goal setting, planning, implementation and follow up are the sole responsibility of the licensee. On the other hand, the regulator has a legitimate right to try to understand how these processes are carried out by the licensees. Going beyond that and asking, for example, for information not available publicly in reports to stakeholders could, however, not be considered appropriate.

5.10 Promotion of safety culture

Safety culture was introduced in the nuclear field after the Chernobyl accident. IAEA made its first attempt to define the term in 1994 and after that several guiding documents have been published which aim to define the concept and put it into operational use at the nuclear facilities. The introduction of safety culture as a concept has undoubtedly been important for the recognition of the safety influence that issues connected to organisation and management may have.

The problem in introducing safety culture into the day-to-day operation at the nuclear facilities is connected to the ambiguity of the concept. In one way, it seems to encompass everything with a connection to safety and, in another way, it is very difficult to get a tangible explanation of what it is and how it should be assessed. There have been a few recent documents (IAEA, 2002c), which have tried to resolve this confusion but there are still many difficulties remaining. In this light, it seems ambitious to enter large inspection programmes that aim to identify early signs of a potentially weak safety culture

(OECD/NEA, 1999). Certainly, if other indicators point towards safety problems they should result in enhanced regulatory attention, follow-up regulatory responses and perhaps, even, to regulatory intervention (OECD/NEA, 2000b). Regulatory intervention based only on deficiencies in safety culture and not on other concrete examples of deficiencies seems to be a bad policy.

Safety culture has become a buzzword in many regulatory regimes. Culture is, however, according to common theories deeply buried into almost unconscious attitudes and beliefs that exist within an organisation and it is an emergent property. It is also apparent that organisations nurture many and not only one organisational culture. At the same time it seems that people have their own interpretations on what is meant by the concept of safety culture. In practice it may, therefore, be more productive to use the concept of safety culture as a pivot point of discussions within the organisation on different means for building a good safety culture (Wahlström and Rollenhagen, 2004). This use of safety culture also has the benefit of enhancing the understanding of different components of safety as provided by different functions in the organisation.

6 Some reflections

The complaints on regulatory oversight by the nuclear industry seem to be based on a feeling that some actions, interventions and requirements are not legitimate in the larger picture of ensuring that the nuclear facilities are safe. The only possibility of combatting such feelings is to open up a discussion on the means and ends of regulatory oversight. If controversies regarding the interpretation of various requirements can be minimised it can be assumed that the regulatory oversight becomes more effective. This chapter brings forward some personal reflections on regulatory oversight based on the challenges and complaints as discussed earlier in this paper. The intention here is not to provide solutions but to give a few anchoring points for the continuing dialogue between the regulator and the industry.

6.1 The need for regulatory control

On the most general level the need for regulatory control can always be questioned. If, for example, society could rely on an internal self-control of the nuclear industry it would at least, in principle, be possible to drastically reduce the need for regulatory oversight. On the other hand, one may argue that self-control cannot give an over-riding priority for safety because it will be intermingled with other considerations. Another argument is that some policing function is always necessary to ensure that actors in a society are not stepping outside agreed boundaries for allowed actions. A third argument is that an independent body is needed to give the general public an assurance that the nuclear industry actually fulfils agreed safety requirements. Perhaps the largest benefit with the regulatory system is that the licensees are forced to make an account of the safety provisions; in that process it is easy to detect earlier mistakes and errors.

Nuclear power has the aspect that the consequences of an accident are not confined to national borders and, therefore, that it is necessary to ensure that all users of nuclear power stick to agreed safety concepts. The Convention on Nuclear Safety has been created as an important instrument to enable a better transparency of the safety oversight.

The national reports written under the obligation of the Convention actually provide very good insights to national systems for regulatory oversight.

6.2 Requirements on regulatory oversight

There are many requirements that can be set on regulatory oversight, such as that it should be anchored in legislation, have clear definition of mission, tasks and mandate, be documented and transparent, be accepted and felt to be legitimate, etc. It is not the intention in this connection to list these requirements but, instead, to discuss the process of arriving at requirements that can be placed on a regulatory system.

In an attempt to define a set of reasonable requirements on regulatory oversight, it is important to start from the task that is given to the regulator from the society. This task can, on the highest level, be seen as requiring, assessing and accepting the evidence necessary to make a convincing case that a specific nuclear facility is sufficiently safe. The question of what should be considered safe enough is a matter of political agreement in the society, where the risks of nuclear power are considered in comparison with its benefits and other risks. Implicit in this task is the assumption that the nuclear power plants are forced to shut down if they are not considered safe.

The regulatory system can be seen as a system of methods and tools which ensure objectivity, consistency and transparency in the regulatory decision making. The regulatory system can also be motivated with arguments of fairness and impartiality towards the licensees. There are certain mutually accepted rules that should be applied as preconditions for plant operation and it is clear that these rules should be made explicit. An interpretation of these rules is then easier and can enhance the communication between the regulator and the licensee by providing intermediate steps of agreement on what can be considered as safe enough.

Going back to the regulatory task it can, on the highest level, be interpreted to imply that the regulator has the right to know, i.e. to access any document or information that can be considered necessary in constructing a chain of evidence from general safety principles to actual solutions in design and operation. When the regulator makes a request for such information it is important that the licensee understands that it does not mean suspicion of wrongdoing but, instead, that it is a completely normal part of regulatory oversight.

6.3 Interactions between the regulator and the licensees

Regardless of the selected regulatory system, there is still the need to describe the intent and content of the regulatory oversight in some detail. Without such descriptions, regulatory oversight easily becomes arbitrary, non-transparent and inequitable. Regulatory oversight has, also, to be defined in internal management and quality handbooks which define the means and ends of regulatory oversight for the inspectors in their work.

The most important stakeholder in the regulatory oversight is the licensee. To ensure a smooth communication it is important that both parties have a clear understanding of their roles and tasks. The regulator has the role of acting as a representative for the society in guarding its members from undue threats to life and limb. The role of the licensee is to build and operate the nuclear facility according to agreed requirements. This also means that the regulator should never interfere with plant management but only set the frame within which the plant is built and operated.

The deregulation of the electricity supply has changed many things for the nuclear utilities and the result has been an increased cost pressure on the operators of the facilities (OECD/NEA, 2000b). This cost pressure has brought a larger hesitance by the licensees in responding to regulatory interventions that are not considered to be cost effective. To some extent, there may have been an earlier indulgence in withstanding regulatory requests when the costs of responding could be recovered in the electricity tariffs. The result is that one can sense a hardened regulatory climate, which is putting strains on earlier relationships.

Responding to these issues would imply the existence of some mechanisms which can initiate a counterforce if a regulator puts an undue pressure on a licensee. Such a mechanism is not likely to be implemented as a super-regulator regulating the regulators but should rely on a continuing dialogue between the regulator and the licensees. Only a good deal of mutual respect and trust can ensure that this dialogue takes place.

6.4 Systems of safety requirements

Systems of safety requirements play an important role in regulatory oversight. The basic dilemma is to manoeuvre between the need to have a restricted system and still to be able to answer questions that may come up in inspection and review. Research has suggested an approach to this dilemma in the concept of formal axiomatic systems. This basic thought is shortly introduced in the two paragraphs below.

A system of safety requirements can be seen as a formal system of axioms and theorems. The axioms would then represent the basic safety principles by which derived requirements, the theorems, can be constructed. According to the famous result of Kurt Gödel, any formal system contains either contradictions or unprovable theorems. This can be interpreted, for instance, as follows; if one wants to ensure that there are no contradictions, one has to accept that certain theorems are unprovable. This actually means any system of requirements always will be incomplete, i.e. there may always be a need for new requirements that cannot be deduced from the existing basic safety principles.

Another path of reasoning about requirements can be borrowed from the field of artificial intelligence. The first generation of expert systems were usually built based on a large set of rules. This way of realising automated reasoning was hampered by the fact that it was almost impossible to validate the correctness of the suggestions they generated because the large amount of rules made the results non-traceable. Another way to build an expert system is to use automated reasoning based on a smaller set of rules which can more easily be verified to be correct. The same principle could be applied for the system of requirements to decrease the number of basic requirements and to generate the necessary derived requirements as the design of a system goes along.

Another dilemma is connected to the responsible actors for creating a consistent system of requirements. It is an inbuilt presumption that safety performance should improve with an accumulation of experience. The difficult issue is who should be responsible for taking the lead and how the safety requirements should be developed. To what extent should they rely on the activities of national regulators and to what extent on consensus building among subject matter experts from the whole field? Present practices for the development of international standards give one answer to this question because they are based on a consensus in international working groups of subject matter experts. However, national regulators also seem to take many initiatives to bring in new regulation into the international arena.

In the development of systems of requirements it is important to remove outdated parts. Unfortunately, the nuclear field seems to be very hesitant in removing old requirements which means that the systems have become cumbersome. One remedy might be to introduce a clear structure in the systems of requirements where high level requirements are expected to have a longer lifetime than low level requirements.

6.5 Establishing a licensing base

One of the crucial questions in regulatory oversight is the amount of mutual trust and confidence that is possible in the interactions between the regulator and the licensee. If the regulator can trust the licensee there is no need to redo the same calculations that have been done e.g. for design purposes. It is also evident that it is not practical to check all chains of evidence in the process of inspecting and reviewing. This question is related to the amount of self-assessment that can be accepted as valid in the regulatory oversight. It is clear that many consecutive layers of inspection and review are not likely to provide additional safety.

A transfer towards risk informed regulation implies a successful integration of deterministic and probabilistic requirements. Today there is no clear view on how this integration should be achieved. The basic principle is that deterministic requirements can be relaxed if the associated sequences can be shown to have a very low probability. Similarly, it should be possible to exclude certain branches in a fault tree based on a deterministic reasoning. The question here is whether there is a need for new thinking to make this integration smoother. It is evident that there is a mounting need for integrated approaches because upcoming applications, such as new regulation for old plants and the licensing of digital I&C systems, create difficult decision making situations.

The licensing of technical systems is fairly well established but it has been shown to be more difficult to agree on the requirements to be placed on the human and organisational systems and how they should be inspected. Also, here there are needs to go deeper into the more philosophical considerations on how safety is constructed, what kind of requirements would be reasonable and what kind of evidence they would need.

6.6 Finding a proper regulatory balance

The regulatory system can be seen as the outcome of a balance between several conflicting demands. It should not be too detailed but it should still be written to have enough detail to be practical in giving guidance both for designers and inspectors. It should be written with the aim of being technologically independent but with the understanding that it may be necessary to illustrate some of the important concepts with specific examples in the use of a specific technology. In searching for a good approach to the regulatory system it is important to note that a strict and competent regulator always is the best counterpart for a nuclear utility or vendor in finding good solutions for problems that may emerge. If there is a mutual agreement that the requirements are sound, they are most likely well balanced.

Looking to the future, perhaps the hardest challenge is to find, develop and accept innovative solutions for the technical, human and organisational systems. It is a sound requirement that only proven technologies should be used but stressing this principle too much may conserve the nuclear field into outdated practices. There is evidently a need to find acceptable practices by which new solutions may be tested, perhaps in a smaller context, to get the experience needed.

One important component in striving for a balanced regulatory oversight is a continuous assessment of regulatory performance. It is not possible to do such an assessment based only on self-assessments or peer reviews. To get a true picture, it is also important that other stakeholders can give their own views. In view of the importance of the interactions between the regulator and the licensees it is clear that representatives from the licensees should be able to give their views on problems and the need for improvements (Wahlström and Sairanen, 2001). Most of the difficulties that can be seen in the regulator licensee interactions are generic and the result of understandable difficulties but they can most likely, to a large extent, be removed in an open dialogue. One problem, however, is that if the dialogue between the regulator and the licensee is too close, it may be attacked by nuclear opponents but a move towards more adversarial regulatory practices can only have a negative influence on safety.

6.7 Regulation within the society

In considering regulation in nuclear safety it is important to remember that, also, other regulators control activities at the nuclear facilities. Such regulators take, for example, a stand on areas such as labour safety, technical safety, environmental protection, market competition, security, etc. It would be beneficial if a harmonisation in these regulatory approaches could be achieved because very large differences sometimes create difficulties. The only way to reach this goal is a creation of a better understanding of similarities and differences between various approaches to implement regulatory oversight (Lindblom et al., 2003).

Nuclear power has a tradition of a broad co-operation between the facilities. This co-operation has, undoubtedly, had a large contribution to the high safety level that has been reached. The deregulation of the electricity market has, however, brought difficulties in maintaining these contacts. The difficulties range from a smaller willingness to share experience to a regulatory prohibition of certain co-ordinating activities between the nuclear utilities to share common resources.

To respond to these issues it seems to be necessary to have some forum where safety and risks on a societal level can be discussed. Unfortunately, at present, there seems not to be any such institution or forum which could take such a broad perspective. Still there are many national and international initiatives which have identified the need for a better co-ordination in the handling of various vulnerabilities in the society.

6.8 Regulation in a global world

Recent years have demonstrated a transfer to a far more global view on industrial activities in general and also within the nuclear utilities. Today, for example, the electric utilities are typically multi-national with assets in several countries. In this development it seems necessary also to ensure that there is a larger harmonisation between regulatory systems

(IAEA, 2002b). If such a harmonisation is not achieved it may tempt the industry to allocate investments in nuclear facilities to countries where the most understanding regulatory climate is found.

The regulators in Europe have identified this threat and have initiated voluntary activities within the Western European Nuclear Regulators Association (WENRA) to achieve a better understanding of differences in the regulatory systems. It is evident that this activity in the future will lead to a better harmonisation, at least with respect to regulatory requirements. A transfer, however, from the national regulatory systems to an international regulatory agent seems however unlikely but the same function may, in the future, be achieved through a network of national regulators. If this scenario is realised one may expect that some new division of work will take place between actors in the network.

One important path towards an increased harmonisation proceeds through the development of international norms and standards. One important development in this direction has been taken with the development of the so called utility requirements which have been developed as a co-operation between several parties (EPRI, 1995, 1999; EUR, 2000, 2001). Research co-operation between technical support organisations associated with the national regulators is another mechanism which, in the long run, works towards an increased harmonisation. The globalisation may, in the future, lead to a relaxation of the competency of the national regulators, at least in the sense that very special narrow competency will be bought on an international market. This may also change the nature of regulatory decision making in the future. Whatever the development will be, it seems clear that international organisations such as IAEA, OECD/NEA and WANO have important roles to play.

6.9 Towards the future

Looking towards the future, there are many trends that can be identified. One technical trend is that there is a growing complexity, both in the design and the operation of the nuclear facilities and their supporting systems. A societal trend is that there is a continuing demand for an increased safety, both real and perceived. Decision making among stakeholders in the nuclear field will be more complex as there are an increasing number of issues to be weighed together in the decisions. It is expected that the pressures to decrease cost in all phases in the life-cycle of a nuclear facility will continue. Present nuclear power plants will, most likely, go through power upgrades and life extensions in modernisation projects. In these projects there will be an increased reliance on automation and information technology as a means of reducing costs and increasing safety. Not very many new nuclear projects are expected in Europe during the next 25 years but it is not likely that the present reliance on nuclear power will decrease.

All these trends mount new challenges on the regulatory systems. There will also be challenges in maintaining nuclear competency and increasing the attractiveness of the nuclear field in general. To be able to succeed, the nuclear field has to be able to prove its attractiveness. It is likely that this will be possible only if there is a suitable influx of new innovations in the technical, human and organisational systems of the nuclear facilities. The question, then, is how such innovations can be stimulated and diffused throughout the industry. In responding to these challenges the nuclear field cannot isolate itself from rest of the world but it should bring in ideas and solutions from other similar fields such as the flight industry, air traffic control (CAA/SRG, 2003), off-shore, the chemical industry, healthcare services, etc.

7 Conclusions

Regulatory oversight has an important position in ensuring the safety of nuclear power. Present principles of regulatory oversight in the nuclear field define three main regulatory tasks

- definition of conditions and requirements for the facilities
- verifying compliance with the conditions and requirements
- forcing the facilities to be shut down if conditions and requirements are violated.

The safety provisions of the nuclear facilities rely on several safety principles that have been developed over many years and these principles are well reflected in the regulatory systems. In spite of this general consensus on how the safety of the nuclear facilities is constructed, there are astonishingly large differences in national regulatory systems.

There are certain challenges connected to present ways of structuring regulatory oversight. Some of these challenges are connected to selected regulatory strategies and others have a more generic nature. The regulatory oversight has sometimes been shown to create controversies between the regulatory body and the nuclear facilities. The reasons for such controversies can often be found in a deficient communication between the regulator and the licensee.

There are many reasons for trying to generate a better understanding of the regulatory systems and their components. Firstly, there is a clear need for moving from prescriptions to more flexible systems of regulatory oversight. Secondly, a globalisation of industrial activities and nuclear power puts a pressure on the regulatory systems towards an increased harmonisation. Thirdly, an understanding of how the regulatory system contributes to safety in its interactions with the safety management activities at the nuclear facilities can help in developing better day-to-day oversight practices. Finally, an understanding of the components of regulatory systems can contribute to their future development.

An efficient regulatory oversight is assumed to fulfil certain requirements, which means that there is a benefit of making these requirements explicit. The division of roles between the regulator and the licensee puts certain demands on the interaction between the regulator and the licensee. This interaction should be governed by an understanding of the legitimacy and content of regulatory actions. It can be assumed that an open and trustful communication between regulatory oversight and safety management activities at the nuclear facilities will enhance the safety of nuclear power.

An efficient regulatory oversight can be achieved only in a stable regulatory regime. An important precondition is that the regulatory system is understood and accepted which, for the regulatory body, implies that policies, objectives and strategies are stated and made public. This does not, however, diminish the importance of consistency in ruling and practices because, even if regulatory oversight is defined and documented in legislation and management systems, it still depends on the interpretation of senior managers within the regulatory body as to how the regulatory mission is converted into concrete programmes, decisions and actions. This is, perhaps, the most crucial insight senior managers at the regulatory bodies should acquire.

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Notes

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